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Learning Curve of Robotic-assisted Radical Prostatectomy With 60 Initial Cases by a Single Surgeon

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OBJECTIVE: We tracked various proficiency indicators for the learning curve as a single Taiwanese surgeon became familiar with robotic-assisted laparoscopic radical prostatectomy surgeries by performing 60 initial procedures.

METHODS: Between December 2005 and December 2007, 60 consecutive patients were classified into Group 1 (Cases 1–30) or Group 2 (Cases 31–60). Pre-operative clinical characteristics, operative parameters, and postoperative parameters were assessed.

RESULTS: Pre-operative biopsy Gleason scores were significantly higher in Group 2 than in Group 1 (7.03 *vs.* 6.13, $p < 0.01$). The vesicourethral anastomosis time showed a statistically significant reduction from 46.38 minutes in Group 1 to 31 minutes in Group 2 ($p < 0.01$). The continence rate at 3 months in Group 2 was higher than that in Group 1 (97.6% *vs.* 76.7%, $p = 0.052$); the mean duration to continence was shorter in Group 2 than Group 1 (70.26 ± 67.37 days *vs.* 39.63 ± 36.48 days, $p = 0.056$). Group 2 had shorter postoperative stays (3.93 *vs.* 7.33) and longer durations of Foley catheter removal (9.0 *vs.* 7.7) than Group 1, representing a statistically significant difference ($p < 0.01$).

CONCLUSION: After gaining experience by performing an initial 30 robotic-assisted laparoscopic radical prostatectomies, the subsequent 30 surgeries established proficiency as determined by vesicourethral anastomosis time and early continence rate. [*Asian J Surg* 2011;34(2):74–80]

Key Words: laparoscopy, prostate cancer, radical prostatectomy, robotics

Introduction

Prostate cancer is the most common cancer in the United States. In Asia and Taiwan, there is a low incidence of clinical prostate cancer; however, the incidence of prostate cancer has been increasing in recent years.[1,2] Prostate cancer is ranked fifth among the most common male malignancies in Taiwan. The mortality rate has been increasing along with the incidence because most cases are diagnosed at advanced stages. Clinical T1c prostate cancer accounts for 25% of localised prostate cancer surgeries.[3]

The da Vinci robotic surgery system for urological applications was introduced in 1999. The da Vinci system (Intuitive Surgical, Inc.; Sunnyvale, CA, USA) offers several technical advantages for the surgeon, including intuitive finger-controlled movements, 10 times magnification, three-dimensional stereoscopic optics, computer elimination of tremor, end-of-wrist instrument with seven degrees of freedom of range of motion, and scaled-down movement. Since the first robotic-assisted laparoscopic radical prostatectomy (RALP) was performed by Binder and Kramer[4] in Frankfurt in May 2000, use of the technique

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has been increasing worldwide as the preferred surgical treatment for localised prostate cancer. In 2006, over 30,000 robotic prostatectomies were performed, and it is estimated that 48,000 such surgeries (approximately 60% of all radical prostatectomies) were performed in 2007.[5,6] However, RALP is still in its infancy in Taiwan. In Taiwan, six da Vinci surgical systems have been acquired since October 2004. Dr Patel has reported that the initial experience with robotic radical prostatectomy is promising with a learning curve of approximately 20–25 cases required to achieve proficiency.[5] We previously reported changes in indicators of proficiency and short-term outcomes during our experience with an initial 30 cases of RALP performed by a single surgeon; we established proficiency as determined by functional outcomes required approximately 30 cases.[1] We herein report our experience with an initial 60 cases and the associated learning curve and short-term outcomes of RALP as performed by a single surgeon.

Patients and methods

Between December 2005 and December 2007, 60 patients with prostate cancer underwent RALP performed by a single surgeon in our institution. The consecutive patients were divided into two groups classified as Group 1 and Group 2: Group 1 comprised the 1st through 30th cases and Group 2 the 31st through 60th cases. Preoperative clinical characteristics were recorded, including age, body mass index, American Society of Anesthesiologists anaesthetic/surgical risk class, prostate-specific antigen (PSA) levels, free PSA ratio, PSA density, biopsy percentage, biopsy Gleason score, and clinical stage.

Surgical procedure

Our da Vinci robotic training course under Dr Patel was completed at Ohio State University, USA, in October 2005.[1] We keep in touch with our mentor Dr Patel to discuss more details, pitfalls, and tips on performing RALP. The robotic team included a console surgeon, two clinical fellows, one circulating nurse, two scrub nurses, and an Intuitive Surgical Taiwan representative. We performed the RALP procedure as previously described.[1] We imitated Patel's way of performing RALP with minor modifications.[6,7] From cases one to six, a four-arm approach was taken; from case seven onward, we took a three-arm approach with five trocars. The biggest difference between Groups 1 and 2 was in the manner of dealing with the puboprostatic ligaments and dorsal vein complex (DVC). In Group 1, the bilateral puboprostatic ligaments were preserved and the DVC was ligated with one sutured stitch (1-0 vicryl); no placement of a second suture for venous backflow or suspension of the DVC was performed. In Group 2, the bilateral puboprostatic ligaments were excised and the DVC was ligated with one sutured stitch (1-0 vicryl); we then placed a second suture (3-0 Monocryl) to secure the DVC to the pubic bone. Another suture (1-0 vicryl) was placed at the anterior prostate capsule for venous backflow. Dissection of the bilateral pelvic lymph nodes and bilateral neurovascular preservation procedures were discretionary and were determined according to the pre-operative tumour status and intra-operative conditions. Urethrovesical anastomosis using two 16-cm 3-0 Monocryl continuous stitches was performed using the Van Velthoven technique.[8] An 18-French silicon Foley catheter with a 10-mL balloon was inserted. The urinary bladder was then injected intra-operatively with 200 mL normal saline to confirm that there was no leakage.

Data collection

Proficiency indicators were recorded for each surgery, including whether bilateral pelvic lymph node dissection or neurovascular bundle preservation (NVB) were performed, the surgeon's console time, vesicourethral anastomosis time, estimated blood loss, transfusion rate, intra-operative and postoperative complication and conversion rates, and whether a postoperative cystogram was performed. Console time was defined as the time when the surgeon was at the console using the da Vinci instrument from the dropping of the urinary bladder to vesicourethral anastomosis. The operating time was variable with different assistants because of differences in the times required to set up trocars, dock the da Vinci, and remove the specimen.

Radical prostatectomy specimens were fixed, coated with Indian ink, and cut into sequential stepwise sections at 4-mm intervals.[3] The Gleason score, positive surgical margin (PSM) rate, specimen volume, tumour volume, tumour percentage, and node positive rate were recorded.

Postoperative care

Postoperatively, patients were encouraged to ambulate on postoperative day (POD) 1 or 2. Patients were permitted to have sips of water and then resume a regular diet on

POD 1 or 2. The closed wound drainage tube was removed on POD 1 to 3. The intravenous fluid was discontinued on POD 1–3. Patients were hospitalised until removal of the Foley catheter at 7 days after surgery in Group 1. Patients were discharged early and arrangements were made to remove Foley catheters at 7–14 days after surgery. Continence was defined as achieving the use of no pads or only one "security" pad daily. Patients were followed up in outpatient clinics at 1 week and 1 month, and then every 3 months after discharge to evaluate urination, sexual function, and PSA level. We defined PSA or biochemical failure as two serial serum PSA results of > 0.2 ng/mL.[3]

Statistical analysis

All data are expressed as mean ± standard deviation. The SPSS 12.0 for Windows program package (SPSS Inc., Chicago, IL, USA) was used for basic statistical calculations. Statistical analysis was performed using the non-parametric Mann-Whitney *U* test, Fisher's exact test, and Yate's correction of the contingency test as appropriate. A p value of less than 0.05 was considered statistically significant.

Results

Operation outcome

We performed RALP on 60 patients and evaluated proficiency as the surgeon's experience with the technique increased. Patients in Group 2 had higher biopsy Gleason scores than Group 1 (7.03 ± 1.16 *vs.* 6.13 ± 0.90, respectively), ($p < 0.01$), and Group 2 had higher pathological Gleason scores (8–10) than Group 1 (30% *vs.* 6.7%) (Table 1). Group 2 also had higher PSA levels and biopsy tumour percentages than Group 1 although these results were not statistically significant. Table 2 demonstrates the proficiency gained over the second course of 30 RALP surgeries as measured by various procedural indicators. For example, Group 1 patients were evaluated by cystogram more frequently than those in Group 2 (43.30% *vs.* 0%, $p < 0.01$) before removal of the urethral catheter. Anastomosis time was the second parameter showing a significant difference: 46.38 ± 15.41 minutes for Group 1 and 31.00 ± 7.36 minutes for Group 2 ($p < 0.01$). Group 2 also had lower console times, blood loss, and transfusion rates than Group 1, but these were not statistically significant. No significant differences were observed between the groups in the incidence of bilateral pelvic lymph node dissection and NVB. Complications were noted in 5 of the 30 patients (16.7%) in Group 1, including urinary bladder injury with intra-operative repair in two cases, vesico-urethral anastomosis tear in one case, and intra-operative bleeding in one case; these two cases were converted to a mini-laparotomy (5 cm) for repair and to check bleeding. One patient experienced a mild vesicourethral anastomosis stricture at 2 months after surgery. Complications were noted in 3 of the 30 patients (10%) in Group 2, including intra-operative bleeding that required mini-laparotomy (5 cm) to check bleeding in one case, mild vesicourethral anastomosis stricture at 4 months postoperatively in one case, and mild urethral meatal stricture in one case.

Table 1. Pre-operative clinical characteristics of initial 60 cases of robotic-assisted radical prostatectomy

Clinical data	Group 1: Cases 1–30	Group 2: Cases 31–60
Age (yr)	67.27 ± 6.21	63.83 ± 7.34
BMI	24.22 ± 3.15	24.78 ± 2.51
ASA (I/II/III)	5/15/10	8/18/4
PSA (ng/mL)	16.46 ± 18.80	17.31 ± 19.00
PSA density	0.47 ± 0.43	0.47 ± 0.51
Biopsy percentage	15.88% ± 10.47%	21.68% ± 18.87%
Biopsy Gleason score	6.13 ± 0.90	7.03 ± 1.16†
2–4/5–7/8–10	2/26/2	0/21/9*
Clinical stage (T1/T2/T3)	15/15/0	11/17/2

*$p < 0.05$; †$p < 0.01$. BMI = body mass index; ASA = American Society of Anesthesiologists anaesthetic/surgical risk class; PSA = prostate-specific antigen; PSA density = PSA/prostate volume by transrectal sonography.

Table 2. Operation parameters of initial 60 cases of robotic-assisted radical prostatectomy

Factors	Group 1: Cases 1–30	Group 2: Cases 31–60
Console time (hr)	3.75 ± 1.62	3.15 ± 0.58
BPLND	22/30 (73.3%)	21/30 (70.0%)
NVB preservation	16/30 (53.3%)	14/30 (46.7%)
Anastomosis time (min)	46.38 ± 15.41	31.00 ± 7.36*
Blood loss (mL)	314.83 ± 284.05	227.33 ± 176.16
Transfusion rate	4/30 (13.3%)	0/30 (0%)
Complications	5/30 (16.7%)	3/30 (10%)
Cystogram	13/30 (43.3%)	0/30 (0%)*

*$p < 0.01$. NVB = neurovascular bundle; BPLND = bilateral pelvic lymph node dissection.

Table 3. Postoperative parameters of initial 60 cases of robotic-assisted radical prostatectomy

Factors	Group 1: Cases 1–30	Group 2: Cases 31–60
Foley catheter (d)	7.70 ± 2.09	9.00 ± 2.21*
Postoperative stay (d)	7.33 ± 2.32	3.93 ± 1.55*
Surgical margin positive	15/30 (50%)	13/30 (43.3%)
pT2	2/15 (13.3%)	1/14 (7.1%)
pT3	13/15 (86.7%)	12/16 (75.0%)
Specimen volume (mL)	40.23 ± 16.71	43.30 ± 15.00
Tumour volume	8.76 ± 7.97	10.54 ± 9.41
Tumour percentage	21.44% ± 17.78%	27.80% ± 27.53%
Pathology Gleason score	7.10 ± 1.12	7.20 ± 1.06
2–4/5–7/8–10	0/24/6	0/22/8
Node-positive	2/30 (6.7%)	3/30 (10%)
PSA failure at 15 months	6/30 (20%)	4/30 (13.3%)

*$p < 0.01$. PSA = prostate-specific antigen.

Table 4. Continence and sexual function outcomes in initial 60 cases of robotic-assisted radical prostatectomy

Factors	Group 1: Cases 1–30	Group 2: Cases 31–60
Continence (d)	70.26 ± 67.37	39.63 ± 36.48*
within 1 wk	6 (20%)	11 (36.7%)
at 3 mo	23 (76.7%)	29 (96.6%)†
at 6 mo	29 (96.7%)	30 (100%)
at 12 mo	30 (100%)	30 (100%)
Potency at 12 mo	14/16 (87.5%)	11/14 (78.6%)
Bilateral NVB	11/11 (100%)	7/7 (100%)
Unilateral NVB	3/5 (60%)	4/7 (57.1%)
Intercourse at 12 mo	10/16 (62.5%)	8/14 (57.1%)
Bilateral NVB	9/11 (81.8%)	6/7 (85.7%)
Unilateral NVB	1/5 (20%)	2/7 (28.6%)

*$p = 0.056$; †$p = 0.052$. NVB = neurovascular bundle preservation.

Oncologic outcomes

Table 3 shows the clinical and pathologic outcomes for the 60 patients. Group 2 patients had significantly shorter postoperative stays and longer catheterisation times than Group 1 ($p < 0.01$). Group 2 had poorer pathological factors than Group 1, including tumour volume, tumour percentage, Gleason pathology score, and node-positive rates. No statistically significant differences were found. The PSM rate and PSA failure rate between the two groups were similar. Postoperatively, patients with PSM underwent no adjuvant radiation or hormonal therapy. Salvage radiation was adopted if PSA double time was greater than 6 months. Patient received salvage hormonal therapy if PSA double time was less than 6 months. Later, PSA failure developed in 10 patients; of these, five underwent salvage radiation and five underwent salvage hormonal therapy.

Functional outcomes

The continence rate at 3 months in Group 2 was higher than that in Group 1 (97.6% *vs.* 76.7%, $p = 0.052$), and the mean duration to continence was shorter in Group 2 than in Group 1 (70.26 ± 67.37 *vs.* 39.63 ± 36.48 days, $p = 0.056$). The long-term continence rate at 12 months was 100% in both groups. Sexual function outcomes at 12 months, including potency and intercourse, were similar in both groups (Table 4).

Discussion

The prevalence of clinical prostate cancers between Asians and whites are quite different; however, the incidence of latent prostate cancer in Taiwan is 33%, similar to that in Japan and the United States.[9–11] Years ago, prostate cancer in Taiwan had a low incidence and mortality rate, but these rates have risen rapidly in the past 2 decades according to data from the Health and National Health Insurance Annual Statistics Information Service of Taiwan (http://www.doh.gov.tw/statistic/index.htm). The incidence has increased 16.13-fold from 1.45/100,000 in 1981 to 23.39/100,000 in 2005. Prostate cancer is currently ranked fifth among male malignancies in Taiwan. The mortality rate increased 10.75-fold from 0.8/100,000 in 1981 to 8.6/100,000 in 2007. Brawley et al[12] reported that countries in which dietary fat intake is greater have been shown to have higher prostate cancer mortality rates. This has led some to conclude that dietary fat causes prostate cancer. Pu et al[2] described an increase in fat consumption of 35% from 97 g/day in 1987 to 131 g/day in 1997 in Taiwan. This evidence supports the idea that environmental and lifestyle factors contribute to increasing the incidence and mortality rates of prostate cancer in Taiwan. Another explanation is that community-based screening conducted at medical centres in Taiwan in recent years have reported an overall detection rate of approximately 1%.[3,13]

Previously, we reported that the short-term outcomes of robotic-assisted radical prostatectomy in Taiwan have confirmed that a learning period of approximately 30 surgeries is required to attain basic proficiency.[1] In the present study, comparisons were made between the first 30 cases and the second 30 cases. A single surgeon performed the surgeries in this study to eliminate the variability in learning curves among different surgeons. Patel's procedure was followed to facilitate rapid assimilation of the technical aspects of the robotic approach. It was very important for us to copy their steps entirely as a standard reference with only minor modifications. Over a 36-month period, this surgeon performed 113 of the 150 RALPs performed in this hospital. The anastomosis time was one of the parameters that improved significantly between the initial and later surgeries. In our study, the vesicourethral anastomosis time declined from 46 minutes for the first 15 cases to 31 minutes, representing a significant difference. Ahlering et al[14] reported an anastomosis time of 50 minutes for cases 1–5, 47 minutes for cases 6–10, 36 minutes for cases 11–20, 27 minutes for cases 21–35, and 21 minutes for cases 36–45. In our study, the vesicourethral anastomosis time decreased from 52 minutes for cases 1–15, 41 minutes for cases 16–30, 31.6 minutes for cases 31–45, and 30.3 minutes for cases 46–60. Anastomosis times were not markedly improved because reconstruction of the bladder neck was necessary in several cases. More experience in dissection of the delicate bladder neck and skilful suturing is needed to achieve a rapid anastomosis time. Our console time was 3.75 hours for the first 30 cases; it decreased to 3.15 hours for the second 30 cases. It was not markedly shortened because more detailed, time-consuming procedures were required in the second 30 cases, such as neurovascular nerve preserving and apex dissection. We found that the times for setup of the da Vinci system, trocar insertion, removal of the specimen, and wound closure gradually decreased as the assistant's experience increased. We did not measure the total time because of inherent bias in the use of different assistants. Another significant marker of proficiency that we observed was the rate of performance of a postoperative cystogram to check for anastomosis leakage, which decreased from 43.3% to 0%.

The tamponade effect prevents venous bleeding during pneumoperitoneum of approximately 12–15 mmHg during RALP. The mean estimated blood loss in studies reported in the literature is 75–900 mL.[1,5,6,14–18] Predictably, the reported transfusion rate ranged from 0% to 16.6%, with no transfusions needed in the initial experience reported for several studies.[1,5,6,14–18] In our study, the blood loss and transfusion rate declined from 314 mL and 13.30% in the first 30 cases to 227 mL and 0% in the subsequent 30 cases, respectively.

The greatest advantage of RALP is rapid recuperation and a very short hospital stay. Patel[15] reviewed the length of hospital stay for RALP and reported only 1.08–5.5 days in one study and 1.08–1.5 days in another recent study in the United States. In our series, postoperative hospitalisation was shortened from 7.33 days for the initial 30 cases to 3.93 days for the subsequent 30 cases.

An additional benefit of RALP is better continence rates and an earlier return of continence because of improved preservation of the urethral sphincter and urethral length. A high-quality, three-dimensional endoscopic camera in the da Vinci system provides better visualisation of the apex, allowing the surgeon to finely dissect and preserve the urethral sphincter.[19] Pasticier et al[20] reported that 80% of patients had continence at 9 days. Ahlering et al[14] reported continence rates of 33%, 63%, and 81% at 1 week, 1 month, and 3 months after RALP, respectively. Patel et al[5] reported continence rates of 47%, 82%, 89%, 92%, and 98% at 1, 3, 6, 9, and 12 months, respectively. In our first 30 cases, the continence rates were 20%, 76.7%, 96.7%, and 100% at 1 week and 3, 6, and 12 months after RALP, respectively. In the subsequent 30 cases, the continence rates were 36.7%, 96.6%, and 100% at 1 week and 3 and 6 months. The continence rate at 3 months in the subsequent 30 cases (Group 2) was higher than in the first 30 cases (Group 1) (97.6% *vs.* 76.7%, $p = 0.052$); the mean duration to continence was shorter in Group 2 than in Group 1 (70.26 ± 67.37 d *vs.* 39.63 ± 36.48 d, $p = 0.056$). The time to return of continence was obviously shortened although the p value did not indicate a statistically significant difference because of the limited number of cases. The parameters of continence rate included perioperative factors (body weight, patient age, and prostate volume), anatomical factors (puboperinealis muscle-sparing dissection, trigonal denervation, and preservation of endopelvic fascia), and technical factors (bladder neck preservation, urethral length preservation, mucosal eversion, NVB preservation, and puboprostatic ligament preservation).[20] The probable reason for the relatively good continence results in the initial group (Group 1) is that the puboprostatic ligament-sparing technique in our modified procedure improves the speed of return of urinary continence after radical prostatectomy. Poore et al[21] reported that the median time until continence was achieved after surgery was significantly shorter ($p = 0.01$) for the puboprostatic ligament-sparing group than for the standard method (6.5 and 12 weeks, respectively). Stolzenburg et al[22] also showed that nerve-sparing endoscopic extraperitoneal radical prostatectomy with preservation of the puboprostatic ligaments was able to ascertain recuperation of early continence more than nerve-sparing radical prostatectomy without preservation of the puboprostatic ligaments. Both of these studies reported that the puboprostatic ligament-sparing technique improves the rapidity of return of urinary continence without significantly interfering with surgical margins.[22,23] The biggest difference between Groups 1 and 2 involved the puboprostatic ligaments and the DVC: Group 1, preservation of puboprostatic ligaments; Group 2, suspension of the DVC. Patel's procedure taught us to divide the puboprostatic ligaments and suspend the DVC. Cold scissors were used to divide the urethra, developing a long urethral stump that facilitated vesicourethral anastomosis.[7] The evidence of our results show that preservation of a longer urethral length improved the continence rate at 3 months and shortened the time to continence by about 30 days. Patel et al[24] prospectively analysed 331 consecutive patients who underwent RALP; 94 without the placement of a suspension stitch (Group 1) and 237 with the application of a suspension stitch (Group 2). The suspension stitch during RALP resulted in statistically significantly higher continence rates (92.8% for Group 1 *vs.* 83% for Group 2) at 3 months after the procedure.[24] The preservation of adequate urethral sphincter length is crucial to maintain the continence mechanism after open radical prostatectomy.[25,26] Paparel et al[19] compared the change in membranous urethral length postoperatively and pre-operatively using endorectal magnetic resonance imaging as a measure of recovery time and level of urinary continence after radical prostatectomy. It is also possible that improvement in the recovery of the continence interval was related to the progression of surgical dissection skills to be able to avoid damage to the urethral sphincter.

In our study, the incidence of bilateral or unilateral NVB preservation was similar in both groups, and the potency and intercourse rate at 12 months were also similar. The overall incidence of NVB preservation was 50%. The overall potency rate was 83.3%; 100% for bilateral NVB preservation and 58.3% for unilateral NVB preservation. The overall intercourse rate at 12 months was 60%; 83.3% for bilateral NVB preservation and 25% for unilateral NVB preservation. The factors that influence erectile function include previous sexual function, age, and intraoperative injury of the NVB. Menon et al[27] reported potency and intercourse rates of 82% and 64% in patients younger than 60 years of age, and 75% and 38% in patients older than 60 years, respectively. Recently, the new technique of prostatic fascia preservation and athermal robotic techniques to avoid neurovascular injury have resulted in better potency rates of up to 97% at the 1-year follow-up.[28,29]

With respect to oncological outcomes, the overall PSM was 46.7%. It decreased slightly from 13.3% to 7.1% for patients at pathological stage T2 and from 86.7% to 75% for patients at pathologic stage T3. We also observed a 16.6% PSA failure rate at 15 months related to more advanced tumours, inadequate surgical margins, and occult pelvic lymph node metastasis. In Patel's review, the PSM rate range was 0% to 20% for patients at T2 and 0% to 75% for T3.[15] Ahlering et al[30] reported one surgeon's outcomes from 60 RALP procedures in which the PSM rate for pathological stages > T3 was 50%. Atug et al[29] reported that the PSM tended to diminish from 45.4%, 21.2% to 11.7% as the surgeon's experience increased over approximately 30 cases. Reducing the PSM rate is undoubtedly a challenge for the novice during experience with the initial 60 cases. We conclude that improvement in the surgeon's technique is the best way to reduce PSM and PSA failure rates, and that more than 60 cases are needed to improve oncological outcomes. The learning curve of RALP was nerve-defined. The surgeon with a low surgical volume of retropubic prostatectomy (RRP) will find it easier to achieve this standard. However, surgeons with extensive experience with RRP may "set the bar" higher for the learning curve because of having higher expectations.[31] Dr Smith reported that RALP results comparable with those obtained routinely with RRP were not achieved until after more than 150 procedures.[31] Surgeon comfort and confidence comparable with that with RRP did not occur until 250 RALP procedures had been performed.[31]

In summary, after experience performing an initial 30 robotic-assisted laparoscopic radical prostatectomies by a single surgeon, the subsequent 30 surgeries established proficiency as determined by vesicourethral anastomosis time and early continence rate.

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